



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Application: Mylan Pharmaceuticals, Inc.

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part

1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on December 9, 2016, Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Road, Morgantown, West Virginia 26505 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled Substance	Drug Code	Schedule
Amphetamine	1100	II
Methylphenidate	1724	II
Oxycodone	9143	II
Hydromorphone	9150	II
Methadone	9250	II
Morphine	9300	II
Fentanyl	9801	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company’s own domestically-manufactured FDF. This

analysis is required to allow the company to export domestically-manufactured FDF to foreign markets. Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: August 28, 2017

Demetra Ashley,
Acting Assistant Administrator.

Billing Code 4410-09-P